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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, TUAN VAN	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,631	KUHNS ET AL.	
	Examiner	Art Unit	
	Tuan V. Nguyen	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10 December 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/10/01,05/15/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 recites the limitation "with respect to said delivery device" in line 10, renders the claim indefinite. Appropriate correction is required.

3. Claim 9 recites the limitation "with respect to said delivery device" in line 20, renders the claim indefinite. Appropriate correction is required.

4. Claims 1 recites the limitation "said first and said second members" in lines 13-14. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

5. Claims 9 recites the limitation "said first and said second members" in lines 22-23. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

6. Claims 10-17 are rejected as depending on claim 9 and is similarly indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

   A person shall be entitled to a patent unless –

   (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 5-7, 9, 13-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al (U.S. 6,113,611).

9. Referring to claim 1, Allen et al disclose a surgical fastener system (see Figs. 5A-5C) of individual surgical fasteners comprising: a drive mechanism having distal and proximal ends, drive mechanism comprising a needle 54 or moving member and a sleeve 51 or fixed opposing member, moving member having a sharpened distal end for piercing tissue; at least one surgical fastener 10, each of one surgical fasteners having a proximal end and a distal end; an actuator (head 60 and plunger 52) having at least two sequential positions, first position (see Fig. 5B) for moving said moving member distally and piercing tissue, and a second position (see Fig. 5C) for moving said moving member proximally, thereby deploying said distal end of said fastener.

10. Referring to claims 5-7, Allen et al disclose the fastener is made from super-elastic alloy of nickel titanium (see col 3, lines 58-60) and fastener can be made from any material so long as it is adequately elastic. Here it is noted that stainless steel is used in tissue fastener and it does have an elastic limit.

11. Referring to claim 9, Allen et al disclose a surgical fastener system (see Figs. 5A-5C) of individual surgical fasteners comprising: a drive mechanism having distal and proximal ends, drive mechanism comprising a needle 54 or moving member and a sleeve 51 or fixed opposing member, moving member having a sharpened distal end for piercing tissue; at least one surgical fastener 10, each of one surgical fasteners having a proximal end and a distal end; an actuator (head 60

and plunger 52) having at least two sequential positions, first position (see Fig. 5B) for moving said moving member distally and piercing tissue, and a second position (see Fig. 5C) for moving said moving member proximally, thereby deploying said distal end of said fastener; and a mechanism (stops 62 and 64) which prevents actuator from moving to said second position, after initially moving to first position, until actuator has fully moved to its first position, and from moving to said first position, after initially moving to said second position, until said actuator has fully moved to its second position (see Figs. 5B and 5C).

12. Referring to claims 13-15, Allen et al disclose the fastener is made from super-elastic alloy of nickel titanium (see col 3, lines 58-60) and fastener can be made from any material so long as it is adequately elastic. Here it is noted that stainless steel does have an elastic limit.

13. Referring to claim 17, it is rejected for the same reason as claim 1.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1. Determining the scope and contents of the prior art.
    2. Ascertaining the differences between the prior art and the claims at issue.
    3. Resolving the level of ordinary skill in the pertinent art.
    4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al (U.S. 6,113,611) further in view of Wenstrom (U.S. 6,007,566).

17. Referring to claims 3, Allen et al discloses the inventions substantially as claimed except for the fasteners includes at least one barb extending axially away from said distal end, and one barb extending axially away from said second end.

18. Still referring to claim 3, Wenstrom discloses a fastener (see Figs. 1 and 2) includes at least one barb 32 extending axially away from said distal end, and one barb extending axially away from said second end 40.

19. Still referring to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the fastener, as disclosed by Wenstrom, to incorporate into the device, as disclosed by Allen because this will provide more anchoring force per fastener.

20. Claims 2, 4, 8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al (U.S. 6,113,611) further in view of Wenstrom (U.S. 6,007,566) and further in view of McGarry et al (U.S. 4,509,518).

21. Referring to claim 2, Allen et al discloses the inventions substantially as claimed except for the moving and fixed members have inner surfaces having a plurality projections spaced thereon, said projections engaging said fasteners; the barb engage inner surfaces of moving and fixed member

22. Still referring to claims 2, McGarry et al disclose a apparatus for applying surgical clips to tissue (see Figs. 2 and 12-14) includes a moving member 92 and fixed member 94 have inner surfaces having a plurality projections 102 and 104, respectively, spaced thereon, and projections engaging fasteners 36.

23. Still referring to claim 2, Wenstrom discloses a tissue fastener substantially as claimed.

24. Still referring to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the fastener delivery device, as disclosed by McGarry et al, to incorporate into the device, as disclosed by Wenstrom, then to incorporate into the device, as disclosed by Allen because this will provide surgeon the ability to apply more anchoring devices to target site without reloading the applicator.

25. Claims 4, 8, and 16 are rejected for the same reason as claim 2.

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude"

granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 4-6 of U.S. Patent No. 6,551,333. Although the conflicting claims are not identical, they are not patentably distinct from each other.

28. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,447,524. Although the conflicting claims are not identical, they are not patentably distinct from each other.

29. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No.

6,425,900. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,830,221 to Stein et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
September 21, 2005

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SUPERVISORY PATENT EXAMINER
10/2/05